

## **REMARKS**

In response to the Office Action, claim 6 has been amended to overcome the 35 USC 112, second paragraph rejection by providing an antecedent basis for “the longitudinal axis.” The Examiner is thanked for pointing this out. Support for the new language is found in Figure 1 and in the original disclosure at page 8, line 19-page 9, line 2.

The Examiner referenced a claim objection (and a 35 USC 112 rejection) of claim 1. Applicant believes this should be claim 6. Claim 6 was amended to correct an informality. The spelling of “male” was corrected. The Examiner is thanked for pointing this out. Claim 6 has also been amended to include a description of the first strap having “a plurality of barbs on the ventral surface for engaging the tissue.” Support for the new language is found in Figures 1, 2a, 3a and 3b and in the original disclosure at page 4, lines 14-16. No new matter has been added by the amendments to Claim 6.

Claim 7 has been amended to include the “proximal end” in reference to the portion of the first and second strap, which is placed in the fascia. Support for the language is found in Figure 1 and in the original disclosure at page 7, line 6, and page 8, lines 9-13. No new matter has been added by the amendments to Claim 7.

Claims 6-8, 13, 16 and 17 remain in the application. Favorable reconsideration is respectfully requested.

### **Amended Claim 6**

Claim 6, as newly amended, now recites a wound closure device for connecting tissue which comprises isolated first and second flexible straps. The first flexible strap, i.e., the male strap, has a proximal and distal end and a ventral and dorsal surface. The second flexible strap, i.e., the female strap, has a proximal end with a female connector and a distal end. As now recited, the female connector includes an opening transverse to the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface. The opening is intended to receive the proximal end of the first or male flexible strap. Applicant submits that claim 6, as now recited, is neither disclosed nor suggested by the cited prior art.

In view of the amendment to claim 6, applicant respectfully submits that claims 6-8, 13, 16 and 17 are in allowable condition.

**Claim Rejections - 35 USC § 102**

Claims 6-8, 16 and 17 are rejected under 35 USC § 102(b) as being anticipated by U.S. Patent 4,950,284 to *Green et al.*

The Examiner alleges that *Green* teaches a wound closure device for connecting tissue (10) comprising at least one pair or isolated first (14) and second (13) flexible straps wherein:

- a. the first flexible strap (14) has a proximal end with a male connector and a distal end, and a ventral and a dorsal surface (referring to Fig. 7); and
- b. the second flexible strap (13) has a proximal end with a female connector (19, 22) and a distal end, and a ventral surface and a dorsal surface, wherein the female connector is configured to adjustably connect to the male connector of the first strap (Fig. 6), wherein the female connector includes an opening transverse to the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface for receiving the male connector (Fig. 10), wherein the first strap and the second strap have a plurality of barbs (26, 21) on the ventral surface for engaging the tissue, and whereby the straps form a wound closure (Fig. 1).

The Examiner is incorrect in his assessment of the first and second straps having a plurality of barbs.

As illustrated in Fig. 4 of *Green*, the “second” strap includes two barbs 26. However, reference number 21 is not a barb and, further, is not on the first strap 14. Referring now to the specification at column 3, lines 5-9, reference number 21 refers to a web which extends between and in perpendicular relation to the flanges 20 to form an opening or slot 22 which is sized for passage of the strap 14. In contrast, claim 6 recites a first strap having a plurality of barbs on a ventral surface for engaging tissue and a second strap having a plurality of barbs on the ventral surface for engaging tissue. This is neither disclosed nor suggested in *Green*.

The Examiner rejects claim 7, stating that *Green* teaches the device of claim 6 wherein the first strap and the second strap are placed in the fascia of the wound, referring to Fig. 7. As illustrated in Fig. 7, the second strap 13 is not placed in the fascia of the wound. Rather, it only covers the surface of the wound. Claim 7 now specifically recites that the proximal end of the first strap and the proximal end of the second strap are placed in the fascia of the wound. The Examiner is reminded that the fascia is a specific layer of the skin below the surface layer.

Claims 8, 16 and 17 all depend directly or indirectly from claim 6. As such, these claims should be in allowable condition.

### **Claim Rejections - 35 USC § 103**

Claims 6-8, 16 and 17 are rejected under 35 USC § 103(a) over U.S. Patent 5,931,855 to *Buncke* in view of U.S. Patent 4,730,615 to *Sutherland et al.*

The Examiner states that *Buncke* teaches a wound closure device for connecting tissue comprising at least one pair of isolated first and second flexible straps which are designed to be adjustably connected to each other, referring to Fig. 6, wherein the first strap and the second strap have a plurality of barbs on the ventral surface for engaging the tissue and whereby the barbs form a wound closure. The Examiner further states that *Buncke* fails to teach wherein the ends of the strap comprise a male connector with a ratcheted surface and a female connector with a buckle, respectively, and the female connector is configured to adjustably connect to the male connector of the first strap, wherein the female connector includes an opening transverse to the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface for receiving the male connector.

The Examiner relies on *Sutherland* to teach a device for connecting tissue wherein one end of the device comprises a male connector 18 with a ratcheted surface 22 and the other end comprises a female connector 12 with a buckle, and the female connector is configured to adjustably connect to the male connector, wherein the female connector 12 includes an opening transverse the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface for receiving the male connector (Fig. 2) in order to provide a device for closing tissue with a locking means to prevent backward movement once it is

engaged. The Examiner states that it would have been obvious to one of ordinary skill at the time the invention was made to modify the device of *Buncke* with the locking configuration of *Sutherland* in order to provide a device for closing tissue with a locking means to prevent backward movement of the device once it is engaged, and further provide a locking mechanism that avoids problems such as inadequate material strength of the knot tied in the two ends, and takes less time and effort to implement in surgery.

The combination of *Buncke* and *Sutherland et al.* is misplaced. *Sutherland et al.* describes a sternum closure device with a head portion, a tail portion and a flexible spine portion. The device appears most like a garbage bag closure device, commonly known as a zip-tie. *Sutherland et al.* is directed to a single device whereby the distal tail is threaded through the sternum and brought back to the proximal head. The tail passes through the head and is locked in place by serrations on the spine engaging a tang in the head portion. The tail is covered in stainless steel to assist in the piercing of the sternum and threading back to the head portion. The spine and head are made of a bio-compatible polymer. While both inventions may be considered to be in the medical device field, the inventions have two distinct purposes and can only be regarded as nonanalogous art. *Buncke* is used to suture skin and *Sutherland et al.* is only meant to suture the sternum. A closure device used to suture skin cannot be simply modified to suture bone because of the tensile requirements in the substrate used to connect the tissue. (MPEP 2143.01VI) Further, it is a basic tenet of the law of obviousness that the prior art must provide some kind of motivation for a skilled artisan to select, combine and/or modify features of references to render an invention obvious (MPEP 2143). If there is no such motivation to support the selection, combination and/or modification, the obviousness rejection is made in hindsight and must be withdrawn. Further still, the very fact that there is no device in the medical field to date, with the exception of the presently claimed invention, which includes isolated first and second straps as recited in claim 6, is evidence of non-obviousness.

Claim 13 is also rejected under 35 USC § 103(a) as being unpatentable over the combination of *Buncke* and *Sutherland* as applied to claim 6 above, and further in view of U.S. Patent 6,241,747 to *Ruff*.

Relying on the assertion that *Buncke* and *Sutherland* teach all the limitations of independent claim 6 as described previously, the Examiner admits that *Buncke* and *Sutherland* fail to teach the utilization of a trochar to insert the first and second straps into the wound. *Ruff* teaches the use of a trochar to assist in insertion of a single tissue connector into a wound in bodily tissue.

As explained above, the combination of *Sutherland* and *Buncke* do not teach or suggest all the features and limitations in claim 6. Therefore, the trochar disclosed in *Ruff* is only applicable to dependent claim 13. When viewed as a whole, all of the features in the present invention are not rendered obvious by *Buncke*, *Sutherland* and *Ruff*. The suggestion to combine *Ruff* and *Buncke* is not apparent in either of the disclosures. The trochar in *Ruff* is meant to assist the surgeon in inserting the connector into the tissue. The trochar is needed because the design of the *Ruff* connector, as shown in Figs. 4 through 11, have only negligible space between the tip of the connector and the next successive barb. Because of this design, the connector immediately faces resistance when inserted into the tissue. In order to properly insert the connector through the tissue, the surgeon must either squeeze the tissue so that the connector must only transverse a smaller area, or the connector must be made of a very rigid material. *Ruff* laments the “tendency of an inserted connector 2 to cut through tissue.” Column 3, line 44. Thus, the *Ruff* invention requires the trochar to maintain tissue intact. In direct contrast, *Buncke* utilizes, discloses and claims a needle to which its connector is attached. The surgical needle in *Buncke* has a sufficient length so that the surgeon may pierce the first and second pieces of tissues, often before any of the exterior barbs encounter resistance in the tissue. The needle facilitates the insertion and pull-through in such a way that a trochar is not needed to practice *Buncke*. Similarly, *Sutherland* claims a tail portion “having a sharpened needle integral with the spine portion to pierce intercostal tissue.” Claim 1, column 4, lines 40-46. The sharpened needle allows the closure device of *Sutherland* to capably pierce the sternum without the closure device encountering any resistance from barbs. The addition of a trochar would not improve *Sutherland*.

## CONCLUSION

Applicant submits that the application is now in condition for allowance. Early notification of such action is earnestly solicited. Should the Examiner have any questions or comments with respect to the application, the Examiner is requested to contact the undersigned attorney. The attorney welcomes and encourages telephone calls related to this application because this may allow the resolution of any disputed claim language and/or other informalities more rapidly and efficiently than by any other means. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

Respectfully submitted,

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